8EHQ-1094-13224 (1)

RHÔNE-POULENC

RHÔNE-POULENC INC.
SPECIALTY CHEMICALS DIVISION
CN 7500, CRANBURY, NJ 08512-7500
TELEPHONE (609) 860-4000

94 OCT 18 PM 2:35

(A)

ORIGINAL

October 12, 1994

8EHQ-94-13224
INIT 10/18/94

CERT. MAIL #P 361 564 942
RETURN RECEIPT REQUESTED

88950000014

OPPT Document Processing Center
Attn: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
401 M"Street, S.W.
Washington, DC 20460

Contains No CBI

RE: TSCA §8(e) Notification of Substantial Risk

Dear Sir or Madam:

Rhone-Poulenc Inc. is providing this notice to the Agency in accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA). The information provided herein was discovered on September 26, 1994 as an outcome of the internal review of off-site archives in which technical data from Alcolac, Inc. (Alcolac)[1] was stored. The box in which these studies were found was labeled "Records 77-79". Upon discovery of these studies, the information was reviewed for consideration of TSCA §8(e) reporting. Summary data is as follows:

01 1. **"Primary Dermal Irritation in Rabbits" - 15% Alconate L-3, Control No. RAS-3-62-5"** - Primary dermal irritation index of 3.15 (severe). The chemical identity of this product is "Poly(oxy-1,2-ethanediyl), alpha-(3-carboxy-1-oxosulfopropyl)-omega-hydroxy-, C10-C16 alkyl ethers, disodium salts" (CAS# 68815-56-5).

02 2. **"Primary Dermal Irritation in Rabbits" - 15% Sipoteric 1398, Control No. RAS-3-62-3"** - Primary dermal irritation index of 5.03 (severe). The chemical identity of this product is "Imidazolium compounds, 1-[2-(carboxymethoxy)ethyl]-1-(carboxymethyl)-4,5-dihydro-2-norcoco alkyl, hydroxides, sodium salts" (CAS# 68650-39-5).

[1]In the late 1980's, Rhone-Poulenc acquired several small specialty chemical companies including Alcolac in 1989.

RECEIVED 10/16/94

07 3. **"Primary Dermal Irritation in Rabbits" - 15% Sipoteric COB, Control No. RAS-3-62-4"** - Primary Irritation Index of 5.13 (severe). The identity of this material is not known.

03 4. **"Primary Dermal Irritation - Akypo RLM-45N (15%), Control No. RAB-8-230"** - Primary Irritation Index of 3.13 (severe). The chemical identity of this product is a mixture of "Poly(oxy-1,2-ethanediyl), alpha-(carboxymethyl)-omega-dodecyloxy-, sodium salts" (CAS# 33939-64-9) and "Poly(oxy-1,2-ethanediyl), alpha-(carboxymethyl)-omega-tetradecyloxy-, sodium salts" (CAS# 50546-32-2).

08 5. **"Primary Dermal Irritation in Rabbits, Primary Ocular Irritation in Rabbits - Surfactant, RAS-3-295-4"** - Primary Dermal Irritation Index of 5.10 (severe), but a moderate ocular irritant. The chemical identity of this product is "Sulfuric acid, monododecyl ester, ammonium salt" (CAS# 2235-54-3" (active).

04 6. **"Primary Dermal Irritation in Rabbits, Primary Ocular Irritation in Rabbits" - Surfactant, RAB-9-278** - Primary Dermal Irritation Index of 5.33 (as is), (severe), and a severe ocular irritant in the unwashed eye (due to the high irritation scores at study termination). The identity of this material is not known.

05 7. **"Primary Dermal Irritation in Rabbits" - Silky Liquid Soap, Control No. RAS-3-23-2"** - Primary Irritation Index of 4.53 (severe). The identity of this material is not known.

06 8. **"Primary Dermal Irritation in Rabbits" - Hand Soap, Control No. RAS-3-54-1** - Primary Irritation Index of 4.95 (severe). The identity of this material is not known.

10 9. **"Primary Dermal Irritation" - Hand Soap, Control No. RAS-3-62-1** - Primary Irritation Index of 4.00 (severe). The identity of this material is not known.

09 10. **"Primary Dermal Irritation in Rabbits, Primary Ocular Irritation in Rabbits" - Surfactant, RAS-3-295-1** - Primary Dermal Irritation Index of 4.20 (severe), but a moderate ocular irritant. The identity of this material is not known.

11 11. **"Primary Dermal Irritation in Rabbits, Primary Ocular Irritation in Rabbits" - Hand Soap, RAS-3-295-2** - Primary Dermal Irritation Index of 3.90 (severe), and a severe ocular irritant in the unwashed eye (due to the high irritation scores at study termination). The identity of this material is not known.

13 12. **"Primary Dermal Irritation in Rabbits, Primary Ocular Irritation in Rabbits" - Surfactant, RAS-3-295-3** - Primary Dermal Irritation Index of 4.40 (severe), but a moderate ocular irritant. The identity of this material is not known.

(3)

13. **"Primary Dermal Irritation in Rabbits, Primary Ocular Irritation in Rabbits" - Hand Soap, RAS-3-295-5** - Primary Dermal Irritation Index of 3.70 (severe), but a moderate ocular irritant. The identity of this material is not known.

(12 系)

For those materials in which the identity is unknown, a review of the product line of Alcolac during this time period would indicate that they are developmental surfactant products, which were never commercialized.

Rhone-Poulenc Inc. hereby asserts that none of the information contained herein is confidential business information (CBI). Should you have any questions, or require any further information, please call (609) 860-3586.

Very truly yours,

RHONE-POULENC, INC.

James E. Blum

James E. Blum
Product Safety Compliance Manager

JEB: 94-086L.DOC

Att.

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

FINAL REPORT

Contains No CBI

CLIENT:	Alcolac Inc. 3440 Fairfield Road Baltimore, Maryland 21226
ATTENTION:	Louis J. Nehmsmann, Ph.D. Manager Surfactant Research
TEST:	Primary Dermal Irritation in Rabbits
TEST ARTICLE:	15% Alconate L-3, Control No. RAS-3-62-5
EXPERIMENT REFERENCE NO.:	84457 - 7

Steven Nitka
Laboratory Director

Allen L. Palanker
President

Date December 28, 1984
SN/daw

This report details:

a primary dermal irritation study in albino rabbits,

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 3, 1984

and identified as:

15% Alconate L-3, Control No. RAS-3-62-5

was used as indicated in the Final Report Summaries.

Study Interval: December 18, 1984 to December 21, 1984

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 84457 - 7

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 5, 1984
December 19, 1984
December 28, 1984

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila Johnson, B.S.	- Laboratory Supervisor
Kerry L. Campbell, B.S.	- Technician
Jamie L. Yorkston, B.A.	- Technician
Deborah A. Worman	- Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director of Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: December 28, 1984
CLIENT: Alcolac Inc.
STUDY NO.: 84457 - 7
REFERENCE: P.O. No. 23291V
TEST ARTICLE: 15% Alconate L-3, Control No. RAS-3-62-5

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 3.15

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions or dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and the latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Summaries of all results are found preceding the text.

Table I

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total possible erythema score = 4	
Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score = 4	
Total possible primary irritation score = 8	

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table [1]
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

CONSUMER PRODUCT TESTING CO., INC.

STUDY: 84457-7
CLIENT: ALCOLAC INC.
DATE: 12/18/84

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

15% ALCONATE L-3,
CONTROL NO. RAS-3-62-5

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HR	2	3	2	3
	72 HR	1	1	1	1
2	24 HR	2	2	3	2
	72 HR	1	0	2	1
3	24 HR	2	2	3	3
	72 HR	2	1	2	1
4	24 HR	2	2	3	2
	72 HR	0	0	2	1
5	24 HR	2	2	3	2
	72 HR	0	0	1	0
6	24 HR	2	2	3	2
	72 HR	0	0	1	1
AVERAGE	24 HR	2.0	2.2	2.8	2.3
	72 HR	0.7	0.3	1.5	0.8

COMBINED AVERAGES: 12.6
PRIMARY IRRITATION INDEX: 3.15

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

RAW DATA PAGE NO. 7261

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

FINAL REPORT

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

ATTENTION: **Louis J. Nehmsmann, Ph.D.**
Manager
Surfactant Research

TEST: Primary Dermal Irritation in Rabbits

TEST ARTICLE: 15% Sipoteric 1398, Control No. RAS-3-62-3

EXPERIMENT REFERENCE NO.: **84457 - 5**

Steven Nitka
Laboratory Director

Allen L. Palanker
President

Date ~~December 28, 1984~~
SN/daw

This report details:

a primary dermal irritation study in albino rabbits,

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 3, 1984

and identified as:

15% Sipoteric 1398, Control No. RAS-3-62-3

was used as indicated in the Final Report Summaries.

Study Interval: December 18, 1984 to December 21, 1984

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-158
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 84457 - 5

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 5, 1984
December 19, 1984
December 28, 1984

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila Johnson, B.S.	- Laboratory Supervisor
Kerry L. Campbell, B.S.	- Technician
Jamie L. Yorkston, B.A.	- Technician
Deborah A. Worman	- Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director of Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-158
1275 Bloomfield Avenue • Fairfield, New Jersey 07006

Final Report Summary

DATE: December 28, 1984
CLIENT: Alcolac Inc.
STUDY NO.: 84457 - 5
REFERENCE: P.O. No. 23291V
TEST ARTICLE: 15% Sipoteric 1398, Control No. RAS-3-62-3

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 5.03

This test article is a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

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Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

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Primary Dermal Irritation in Rabbits

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Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
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C	Crust	Scab. Dried exudate on the surface of a lesion.
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S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
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U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

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Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
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5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

CONSUMER PRODUCT TESTING CO., INC.

STUDY: 84457-5
CLIENT: ALCOLAC INC.
DATE: 12/18/84

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

15% SIPOTERIC 1398,
CONTROL NO. RAS-3-62-3

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HR	3	3	3	3
	72 HR	4	2 D,F	4	2 D,F
2	24 HR	2	3	2	2
	72 HR	4	2 D,F	3	1
3	24 HR	3	2	3	2
	72 HR	3	2 D	3	1
4	24 HR	3	2	3	2
	72 HR	4	2 D,F	4	2 D,F
5	5	3	3	3	3
	72 HR	4	2 D	3	1
6	24 HR	3	2	3	2
	72 HR	2	1	3	1
AVERAGE	24 HR	2.8	2.4	2.8	2.2
	72 HR	3.5	1.8	3.3	1.3
	5	3.0	3.0	3.0	3.0

COMBINED AVERAGES: 20.1
PRIMARY IRRITATION INDEX: 5.03

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

RAW DATA PAGE NO. 7259

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

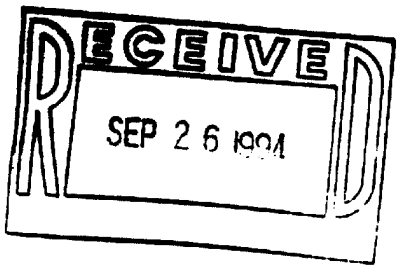
(201) 575-7688
(201) 575-7689

FINAL REPORT

Contains No CBI

CLIENT:	Alcolac Inc. 3440 Fairfield Road Baltimore, Maryland 21226
ATTENTION:	**Louis J. Nehmsmann, Ph.D.** **Manager** **Surfactant Research**
TEST:	Primary Dermal Irritation in Rabbits
TEST ARTICLE:	15% Sipoteric COB, Control No. RAS-3-62-4
EXPERIMENT REFERENCE NO.:	84457 - 6

Steven Nitka
Laboratory Director



Allen L. Palanker
President

Date December 28, 1984
SN/daw

This report details:

a primary dermal irritation study in albino rabbits,

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 3, 1984

and identified as:

15% Sipoteric COB, Control No. RAS-3-62-4

was used as indicated in the Final Report Summaries.

Study Interval: December 18, 1984 to December 21, 1984

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 84457 - 6

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 5, 1984
December 19, 1984
December 28, 1984

Professional personnel involved:

Steven Nitka, B.S.	-	Laboratory Director (Study Director)
Sheila Johnson, B.S.	-	Laboratory Supervisor
Kerry L. Campbell, B.S.	-	Technician
Jamie L. Yorkston, B.A.	-	Technician
Deborah A. Worman	-	Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director of Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing
Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: December 28, 1984
CLIENT: Alcolac Inc.
STUDY NO.: S4457 - 6
REFERENCE: P.O. No. 23291V
TEST ARTICLE: 15% Sipoteric COB, Control No. RAS-3-62-4

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 5.13

This test article is a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions or dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and the latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Summaries of all results are found preceding the text.

Table I

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

CONSUMER PRODUCT TESTING CO., INC.

STUDY: 84457-6
CLIENT: ALCOLAC INC.
DATE: 12/18/84

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

15% SIPOTERIC COB,
CONTROL NO. RAS-3-62-4

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	ED	SITE 2 A ER	ED
1	24 HR	3	3	3	3
	72 HR	1	2 D	3	2 D
2	24 HR	3	3	3	3
	72 HR	4	2 D,F	4	2 D,F
3	24 HR	3	2	3	2
	72 HR	3	1 D	3	1 D
4	24 HR	3	2	3	2
	72 HR	3	2 D	3	1 D
5	24 HR	3	3	3	3
	72 HR	3	2 D	3	2 D
6	24 HR	3	2	3	2 B
	72 HR	3	1 D	4	2 D
AVERAGE	24 HR	3.0	2.5	3.0	2.5
	72 HR	2.8	1.7	3.3	1.7

COMBINED AVERAGES: 20.5
PRIMARY IRRITATION INDEX: 5.13

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

RAW DATA PAGE NO. 7260

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

FINAL REPORT

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

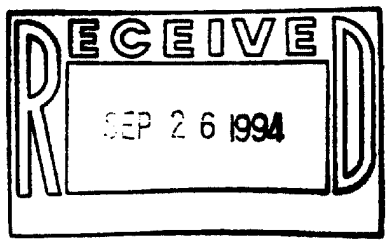
ATTENTION: Louis J. Nehmsmann, Ph.D.
Manager
Surfactant Research

TEST: Primary Dermal Irritation in Rabbits

TEST ARTICLE: AKYPO RLM-45N (15%), Control No. RAB-8-230

EXPERIMENT REFERENCE NO.: 84457 - 13

Steven Nitka
Laboratory Director



Allen L. Palanker
President

Date December 28, 1984
SN/daw

This report details:

a primary dermal irritation study in albino rabbits,

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 3, 1984

and identified as:

AKYPO RLM-45N (15%), Control No. RAB-8-230

was used as indicated in the Final Report Summaries.

Study Interval: December 18, 1984 to December 21, 1984

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue • Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 84457 - 13

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 5, 1984
December 19, 1984
December 28, 1984

Professional personnel involved:

Steven Nitka, B.S.	-	Laboratory Director (Study Director)
Sheila Johnson, B.S.	-	Laboratory Supervisor
Kerry L. Campbell, B.S.	-	Technician
Jamie L. Yorkston, B.A.	-	Technician
Deborah A. Worman	-	Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director of Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: December 28, 1984
CLIENT: Alcolac Inc.
STUDY NO.: 84457 - 13
REFERENCE: P.O. No. 23291V
TEST ARTICLE: AKYPO RLM-45N (15%), Control No. RAB-8-230

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 3.13

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions or dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and the latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Summaries of all results are found preceding the text.

Table I

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total possible erythema score = 4	

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score = 4	
Total possible primary irritation score = 8	

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

CONSUMER PRODUCT TESTING CO., INC.

STUDY: 84457-13
CLIENT: ALCOLAC INC.
DATE: 12/18/84

TABLE 3

PRIMAR SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

AKYPO RLM-45N (15%),
CONTROL NO. RAB-8-230

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HR	3	2	3	2
	72 HR	0	0	0	0
2	24 HR	3	2	3	2
	72 HR	2	1	2	1
3	24 HR	3	2	3	2
	72 HR	0	0	1	1
4	24 HR	2	2	3	2
	72 HR	0	0	1	0
5	24 HR	3	2	3	2
	72 HR	1	0	1	0
6	24 HR	3	2	3	2
	72 HR	1	0	3	1 D
AVERAGE	24 HR	2.8	2.0	3.0	2.0
	72 HR	0.7	0.2	1.3	0.5

COMBINED AVERAGES: 12.5
PRIMARY IRRITATION INDEX: 3.13

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

RAW DATA PAGE NO. 7262

Sipon L22 Sp 15% AS

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

ATTENTION: Robert Stonier

TESTS: Primary Dermal Irritation in Rabbits
Primary Ocular Irritation in Rabbits

TEST ARTICLE: SURFACTANT, RAS-3-295-4

EXPERIMENT REFERENCE NO.: 85552-5

Steven Nitka
Laboratory Director

Allen L. Palanker
President

Date January 8, 1986
SN/mk

This report details:

a primary dermal irritation study, and
a primary ocular irritation study in albino rabbits

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 20, 1985

and identified as:

SURFACTANT, RAS-3-295-4

was used as indicated in the Final Report Summaries.

Study Interval: December 30, 1985 to January 6, 1986

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 85552-5

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 26, 1985
January 2, 1986
January 8, 1986

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila (Johnson) Hamill, B.S.	- Laboratory Supervisor
Joan Breheny, B.S.	- Technician
Philip Lipari, B.S.	- Technician
Kathleen R. (Daly) Paladino	- Animal Care Supervisor
Deborah A. Worman	- Administrative Assistant Member, Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk

Barbara A. Adamczyk, B.S.
Director
Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-5
REFERENCE: P.O.# 24343V
TEST ARTICLE: SURFACTANT, RAS-3-295-4

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour reading were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 5.10

This test article is a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-5
REFERENCE: P.O.# 24343V
TEST ARTICLE: SURFACTANT, RAS-3-295-4

Primary Ocular Irritation in Rabbits

Method: Six (6) New Zealand white rabbits, free from visible ocular defects, each received a single intraocular application of 0.1 milliliter of the test article. The contralateral eye, remaining untreated, served as a control. The eyes of three (3) animals remained unwashed for 24 hours; the eyes of the remaining three (3) animals were washed out 4 seconds after instillation of the test article. Observations of corneal opacity, iritis, conjunctivitis, and other effects were recorded 24, 48 and 72 hours after treatment, and at 4 and 7 days if irritation persisted. The test article was used as received.

	Draize Scores				
	Hours			Days	
Group	24	48	72	4	7
Unwashed	32.3	26.3	16.3	15.0	2.3
4" Wash	2.0	0.0	0.0	----	---

This test article is a moderate ocular irritant to rabbits under conditions of this test. The wash procedure reduced the severity and duration of the irritation observed.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions of dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and a 4 inch Webril pad. The latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Ocular Irritation in Rabbits

This test was designed to determine the ocular irritation potential of substances in both unwashed and washed eyes of rabbits. The procedure followed was a modification of that described by J.H. Draize.[1]

In the technique of determining toxicity of substances to ocular mucosa, observation of injuries was made on the cornea, iris, and the bulbar and palpebral conjunctivae. Numerical scores were assigned to lesions observed according to the Draize scale. (Refer to appended table.) In this system of scoring, the injuries to the cornea and iris account for approximately 80% of the score; these structures are purposely weighted because of their vital role in vision. The presence of lesions not described in the Draize scale was also noted.

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, were obtained through a suitably licensed dealer. The animals were checked carefully upon receipt for ocular defects, diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition. Any animal exhibiting visible ocular defects or irritation, or in poor condition, was not used in this test.

Animals were acclimated for at least 3 days prior to test initiation. They were housed in galvanized or stainless steel cages and identified through individual markings on the outer ear of each animal, as well as a cage label. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum.

Immediately prior to test initiation, the animals were placed in wooden restrainers. A dose of one-tenth (0.1) of a milliliter of the test article was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test article was dropped. The eyelids were gently held together for 1 second. The contralateral eye, remaining untreated, served as a control.

The eyes of the first three (3) animals remained unwashed for 24 hours, at which time, after reading, any excess test article was gently washed out with lukewarm water. The eyes of the remaining three (3) rabbits were irrigated 4 seconds following instillation of the test article, with sufficient lukewarm water at room temperature to wash out all visible test article. Effects of the washout, either beneficial or detrimental, were noted.

Observations of ocular irritation were recorded 24, 48 and 72 hours following instillation of the test article. Additional readings were made at 4 and 7 days if irritation persisted.

Daily scores were determined for each animal using the weighing system at the top of the data table; then mean daily scores were determined for each of the test groups.

[1] J.H. Draize, "Dermal Toxicity', Appraisal of the Safety Chemical in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975,) pp. 49 - 51.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Primary Ocular Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 4 and 5 respectively. The individual results are presented in Table 6.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

CONSUMER PRODUCT TESTING CO., INC.

STUDY: S5552-5
CLIENT: ALCOLAC INC.
DATE: 12/30/85

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

SURFACTANT, RAS-3-295-4

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HRS	2	2 B	2	2 B
	72 HRS	3	3 D	3	2 D
2	24 HRS	2	2 B	2	2 B
	72 HRS	3	3 D	3	3 D
3	24 HRS	2	3 B	2	3 B
	72 HRS	3	2 D	3	2 D
4	24 HRS	3	3 B	3	3 B
	72 HRS	3	3 D	3	3 D
5	24 HRS	2	2 B	2	2 B
	72 HRS	3	2 D	3	3 D
6	24 HRS	2	3 B	2	3 B
	72 HRS	3	2 D	3	2 D
AVERAGE	24 HRS	2.2	2.5	2.2	2.5
	72 HRS	3.0	2.5	3.0	2.5

COMBINED AVERAGES: 20.4
PRIMARY IRRITATION INDEX: 5.10

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

RAW DATA PAGE NO. 7857

Table 4

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	Opacity (A)	
	Opacity - degree of density (area which is dense is taken for reading)	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	Area of Cornea Involved (B)	
	One-quarter (or less), but not zero.	1
	Greater than one-quarter, but less than one-half.	2
	Greater than one-half, but less than three-quarters.	3
	Greater than three-quarters, up to whole area.	4
	Score equals A x B x 5 Total maximum = 80	
Iris	Values (A)	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combinations of any thereof), iris still reacting to light.	
	Sluggish reaction is positive.	1
	No reaction to light hemorrhage, gross destruction, (any or all of these).	2
	Score equals A x 5 Total maximum = 10	

Table 4 (cont'd.)

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctivae	**Redness (A)**	
	Redness (refers to palpebral conjunctivae only). Vessels definitely injected above normal.	1
	More diffuse, crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	Chemosis (B)	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	Discharge (C)	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
	Discharge with moistening of the lids and hairs and considerable area around eye.	3
	Score equals (A + B + C) x 2	Total maximum = 20

Note: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Table 4
(continued)

Scoring Criteria for Eye Reaction - Addendum

Notation	Condition
B	Blanching
BD	Bloody discharge
CE	Corneal Edema
En	Encroachment of Sclera
FVCN	Fibrovascular connective tissue
H	Hair loss around eye
Hm	Hematoma
M	Nodular Mass Subjacent to Meibomian Gland
N	Necrosis
TAC	Test Article Adhering to conjunctivae

Table 5

Eye Irritation
Relative Classification of Test Articles
Based on Grading of Irritation

Rating	Range	Definition
Non-irritating	0.0 - 0.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Practically non-irritating	0.5 - 2.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Minimally irritating	2.5 - 15.0	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating one level.
Mildly irritating	15.0 - 25.0	To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating one level.
Moderately irritating	25.0 - 50.0	To maintain this rating, scores at 7 days must be less than 10 for 3 or more of the animals and mean 7 day scores must be less than 25, otherwise, raise rating one level.
Severely irritating	50.0 - 80.0	To maintain this rating, scores at 7 days must be less than 30 for 3 or more of the animals and mean 7day score must be less than 45, otherwise, raise rating one level.
Extremely irritating	80.0 - 110.0	

TABLE 6

PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

SURFACTANT, RAS-3-295-4

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+				IRIS: A×5(ST2)+		CONJUNCTIVAE: (A+B+C)×2(ST3)=				TOTAL SCORES
UNWASHED												
1	1	1	4	20		1	5	2	2	1	10	35
	2	1	1	5		0	0	3	3	2	16	21
	3	1	3	15		0	0	1	1	0	4	19
	4	1	3	15		0	0	1	1	0	4	19
	7	1	1	5		0	0	0	0	0	0	5
2	1	1	4	20		1	5	2	3	1	12	37
	2	1	4	20		1	5	3	3	2	16	41
	3	2	1	10		1	5	2	2	0	8	23
	4	4	1	20	FVCN	0	0	1	1	0	4	24
	7	0	0	0		0	0	1	0	0	2	2
3	1	1	3	15		0	0	2	2	1	10	25
	2	1	1	5		0	0	2	2	2	12	17
	3	1	1	5		0	0	1	0	0	2	7
	4	0	0	0		0	0	1	0	0	2	2
	7	0	0	0		0	0	0	0	0	0	0
AVERAGE	1											32.
	2											26.
	3											16.
	4											15.
	7											2.

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

TABLE 6
(CONTINUED)
PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

SURFACTANT, RAS-3-295-4

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+	IRIS: A×5(ST2)+	CONJUNCTIVAE: (A+B+C)×2(ST3)=	TOTAL SCORES
		4 SECOND WASH			
4	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
5	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
6	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
AVERAGE	1				2.
	2				0.
	3				0.
	4				-
	7				-

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

Contains No CBI

CLIENT: Alcolac
3440 Fairfield Road
Baltimore, Maryland 21226

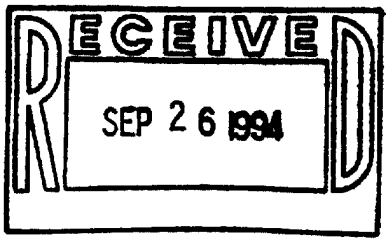
ATTENTION: Robert Stonier

TESTS: **Primary Dermal Irritation in Rabbits**
Primary Ocular Irritation in Rabbits

TEST ARTICLE: SURFACTANT, RAB-9-278

EXPERIMENT REFERENCE NO.: 85535

Steven Nitka
Laboratory Director



Allen L. Palanker
President

Date January 6, 1986
SN/hs

This report details:

primary dermal irritation studies, and
a primary ocular irritation study in albino rabbits

performed at the behest of:

Alcolac
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac

received on:

December 11, 1985

and identified as:

SURFACTANT, RAB-9-278

was used as indicated in the Final Report Summaries.

Study Interval: December 23, 1985 to January 2, 1986

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(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 85535

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 18, 1985
December 26, 1985
January 2, 1986
January 7, 1986

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila (Johnson) Hamill, B.S.	- Laboratory Supervisor
Joan Breheny, B.S.	- Technician
Philip Lipari, B.S.	- Technician
Kathleen R. (Daly) Paladino	- Animal Care Supervisor
Deborah A. Worman	- Administrative Assistant Member, Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director
Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 6, 1986
CLIENT: Alcolac
STUDY NO.: 85535
REFERENCE: P.O.#24286
TEST ARTICLE: SURFACTANT, RAB-9-278

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour reading were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 5.33

This test article is a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

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Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 6, 1986
CLIENT: Alcolac
STUDY NO.: 85535
REFERENCE: P.O.#24286
TEST ARTICLE: SURFACTANT, RAB-9-278

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour reading were averaged to determine the primary irritation index. The test article was used as a 50% volumetric aqueous suspension.

Primary Irritation Index:* 2.80

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

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Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 6, 1986
CLIENT: Alcolac
STUDY NO.: 85535
REFERENCE: P.O.#24286
TEST ARTICLE: SURFACTANT, RAB-9-278

Primary Ocular Irritation in Rabbits

Method: Six (6) New Zealand white rabbits, free from visible ocular defects, each received a single intraocular application of 0.1 milliliter of the test article. The contralateral eye, remaining untreated, served as a control. The eyes of three (3) animals remained unwashed for 24 hours; the eyes of the remaining three (3) animals were washed out 4 seconds after instillation of the test article. Observations of corneal opacity, iritis, conjunctivitis, and other effects were recorded 24, 48 and 72 hours after treatment, and at 4 and 7 days if irritation persisted. The test article was used as received.

	Draize Scores				
	Hours			Days	
Group	24	48	72	4	7
Unwashed	32.7	17.7	16.3	18.3	15.3
4" Wash	2.7	2.0	0.7	0.0	----

This test article is a severe ocular irritant to rabbits under conditions of this test. The wash procedure reduced the severity and duration of the irritation observed.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions of dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and a 4 inch Webril® pad. The latter was held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Dermal Irritation in Rabbits

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Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions or dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article, mixed as indicated in the final report summary, was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze, and a 4 inch Webril® pad. The latter was held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Ocular Irritation in Rabbits

This test was designed to determine the ocular irritation potential of substances in both unwashed and washed eyes of rabbits. The procedure followed was a modification of that described by J.H. Draize.[1]

In the technique of determining toxicity of substances to ocular mucosa, observation of injuries was made on the cornea, iris, and the bulbar and palpebral conjunctivae. Numerical scores were assigned to lesions observed according to the Draize scale. (Refer to appended table.) In this system of scoring, the injuries to the cornea and iris account for approximately 80% of the score; these structures are purposely weighted because of their vital role in vision. The presence of lesions not described in the Draize scale was also noted.

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, were obtained through a suitably licensed dealer. The animals were checked carefully upon receipt for ocular defects, diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition. Any animal exhibiting visible ocular defects or irritation, or in poor condition, was not used in this test.

Animals were acclimated for at least 3 days prior to test initiation. They were housed in galvanized or stainless steel cages and identified through individual markings on the outer ear of each animal, as well as a cage label. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum.

Immediately prior to test initiation, the animals were placed in wooden restrainers. A dose of one-tenth (0.1) of a milliliter of the test article, mixed as indicated in the final report summary, was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test article was dropped. The eyelids were gently held together for 1 second. The contralateral eye, remaining untreated, served as a control.

The eyes of the first three (3) animals remained unwashed for 24 hours, at which time, after reading, any excess test article was gently washed out with lukewarm water. The eyes of the remaining three (3) rabbits were irrigated 4 seconds following instillation of the test article, with sufficient lukewarm water at room temperature to wash out all visible test article. Effects of the washout, either beneficial or detrimental, were noted.

Observations of ocular irritation were recorded 24, 48 and 72 hours following instillation of the test article. Additional readings were made at 4 and 7 days if irritation persisted.

Daily scores were determined for each animal using the weighing system at the top of the data table; then mean daily scores were determined for each of the test groups.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), pp. 49-51.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Tables 3 and 4.

Primary Ocular Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 5 and 6 respectively. The individual results are presented in Table 7.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

CONSUMER PRODUCT TESTING CO., INC.

STUDY: 85535
CLIENT: ALCOLAC
DATE: 12/23/85

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

SURFACTANT, RAB-9-278

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 A ER	SITE 1 A ED	SITE 2 I ER	SITE 2 I ED
1	24 HRS	3	3	3	3
	72 HRS	3	2 D	3	2 D,F
2	24 HRS	3	2	3	2
	72 HRS	3	1 D	3	2 D
3	24 HRS	3	3	3	3
	72 HRS	3	2 D	3	2 D.F
4	24 HRS	3	3	3	3
	72 HRS	3	2 D	3	2 D
5	24 HRS	3	3	3	3
	72 HRS	3	1 D	3	2 D
6	24 HRS	3	3	3	3
	72 HRS	3	2 D	3	2 D
AVERAGE	24 HRS	3.0	2.8	3.0	2.8
	72 HRS	3.0	1.7	3.0	2.0

COMBINED AVERAGES: 21.3
PRIMARY IRRITATION INDEX: 5.33

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

STUDY: 35535A
CLIENT: ALCOLAC
DATE: 12/30/85

TABLE 4

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

SURFACTANT, RAB-9-278

0.5 ML, 50% V/V H20

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HRS	2	1	2	1
	72 HRS	1	0	2	1
2	24 HRS	2	1	2	1
	72 HRS	2	0	2	0
3	24 HRS	2	2	2	2
	72 HRS	2	0	2	0
4	24 HRS	2	1	2	2
	72 HRS	2	0	2	0
5	24 HRS	2	1	2	1
	72 HRS	1	0	2	0
6	24 HRS	2	2	2	2
	72 HRS	2	1	3	1
AVERAGE	24 HRS	2.0	1.3	2.0	1.5
	72 HRS	1.7	0.2	2.2	0.3

COMBINED AVERAGES: 11.2
PRIMARY IRRITATION INDEX: 2.80

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

Table 5

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	Opacity (A)	
	Opacity - degree of density (area which is dense is taken for reading)	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	Area of Cornea Involved (B)	
	One-quarter (or less), but not zero.	1
	Greater than one-quarter, but less than one-half.	2
	Greater than one-half, but less than three-quarters.	3
	Greater than three-quarters, up to whole area.	4
	Score equals A x B x 5 Total maximum = 80	
Iris	Values (A)	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combinations of any thereof), iris still reacting to light.	
	Sluggish reaction is positive.	1
	No reaction to light hemorrhage, gross destruction, (any or all of these).	2
	Score equals A x 5 Total maximum = 10	

Table 5 (cont'd.)

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctivae	Redness (A)	
	Redness (refers to palpebral conjunctivae only). Vessels definitely injected above normal.	1
	More diffuse, crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	Chemosis (B)	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	Discharge (C)	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
	Discharge with moistening of the lids and hairs and considerable area around eye.	3
	Score equals (A + B + C) x 2	Total maximum = 20

Note: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Table 5
(continued)

Scoring Criteria for Eye Reaction - Addendum

Notation	Condition
B	Blanching
BD	Bloody discharge
CE	Corneal Edema
En	Encroachment of Sclera
FVCN	Fibrovascular connective tissue
H	Hair loss around eye
Hm	Hematoma
M	Nodular Mass Subjacent to Meibomian Gland
N	Necrosis
TAC	Test Article Adhering to conjunctivae

Table 6

Eye Irritation
Relative Classification of Test Articles
Based on Grading of Irritation

Rating	Range	Definition
Non-irritating	0.0 - 0.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Practically non-irritating	0.5 - 2.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Minimally irritating	2.5 - 15.0	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating one level.
Mildly irritating	15.0 - 25.0	To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating one level.
Moderately irritating	25.0 - 50.0	To maintain this rating, scores at 7 days must be less than 10 for 3 or more of the animals and mean 7 day scores must be less than 25, otherwise, raise rating one level.
Severely irritating	50.0 - 80.0	To maintain this rating, scores at 7 days must be less than 30 for 3 or more of the animals and mean 7day score must be less than 45, otherwise, raise rating one level.
Extremely irritating	80.0 - 110.0	

TABLE 7

PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

SURFACTANT, RAB-9-278

L EYE

0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+		IRIS: A×5(ST2)+		CONJUNCTIVAE: (A+B+C)×2(ST3)=		TOTAL SCORE*
			UNWASHED					
1	1	1 4	20	1	5	2 2 1	10	35
	2	1 3	15	0	0	3 2 1	12	27
	3	1 3	15	0	0	1 1 1	6	21
	4	4 1	20 FVCN	0	0	1 1 1	6	26
	7	4 1	20 FVCN	0	0	1 1 0	4	24
2	1	1 3	15	1	5	1 2 1	8	28
	2	1 1	5	0	0	1 1 1	6	11
	3	1 1	5	0	0	1 0 0	2	7
	4	1 1	5	0	0	0 0 0	0	5
	7	0 0	0	0	0	0 0 0	0	0
3	1	1 4	20	1	5	1 3 1	10	35
	2	1 1	5	0	0	2 2 1	10	15
	3	1 3	15	0	0	1 1 1	6	21
	4	4 1	20 FVCN	0	0	1 1 0	4	24
	7	4 1	20 FVCN	0	0	1 0 0	2	22
AVERAGE	1							32.
	2							17.
	3							16.
	4							18.
	7							15.

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

TABLE 7
(CONTINUED)
PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

SURFACTANT, RAB-9-278

L EYE

0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+	IRIS: A×5(ST2)+	CONJUNCTIVAE: (A+B+C)×2(ST3)=	TOTAL SCORE*
		4 SECOND WASH			
4	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	1 0 0 2	2
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
5	1	0 0 0	0 0	1 1 0 4	4
	2	0 0 0	0 0	1 0 0 2	2
	3	0 0 0	0 0	1 0 0 2	2
	4	0 0 0	0 0	0 0 0 0	0
	7	- -	-	- - -	
6	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	1 0 0 2	2
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
AVERAGE	1				2.
	2				2.
	3				0.
	4				0.
	7				

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

CLIENT:	Alcolac Inc. 3440 Fairfield Road Baltimore, Maryland 21226
ATTENTION:	Louis J. Nehmsmann, Ph.D. Manager Surfactant Research
TEST:	Primary Dermal Irritation in Rabbits
TEST ARTICLE:	Silky Liquid Soap, Control No. RAS-3-23-2
EXPERIMENT REFERENCE NO.:	84428-1

Contains No CBI

Steven Nitka
Laboratory Director

Allen L. Palanker
President

Date November 19, 1984
SN/lc

This report details: a primary dermal irritation study in albino rabbits

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

November 12, 1984

and identified as:

Silky Liquid Soap,
Control No. RAS-3-23-2

was used as indicated in the Final Report Summaries.

Study Interval: November 13, 1984 to November 16, 1984

201) 575-7688
201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 84428-1

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: November 14, 1984
November 20, 1984

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila Johnson, B.S.	- Laboratory Supervisor
Kevin J. Gorman, B.S.	- Technician
Jamie L. Yorkston, B.A.	- Technician
Deborah A. Worman	- Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director of Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: November 19, 1984
CLIENT: Alcolac Inc.
STUDY NO.: 84428-1
REFERENCE: L.J. Nehmsmann, Ph.D.
TEST ARTICLE: Silky Liquid Soap,
Control No. RAS-3-23-2

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 4.53

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions or dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and the latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Summaries of all results are found preceding the text.

Table I

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total possible erythema score = 4	
Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score = 4	
Total possible primary irritation score = 8	

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

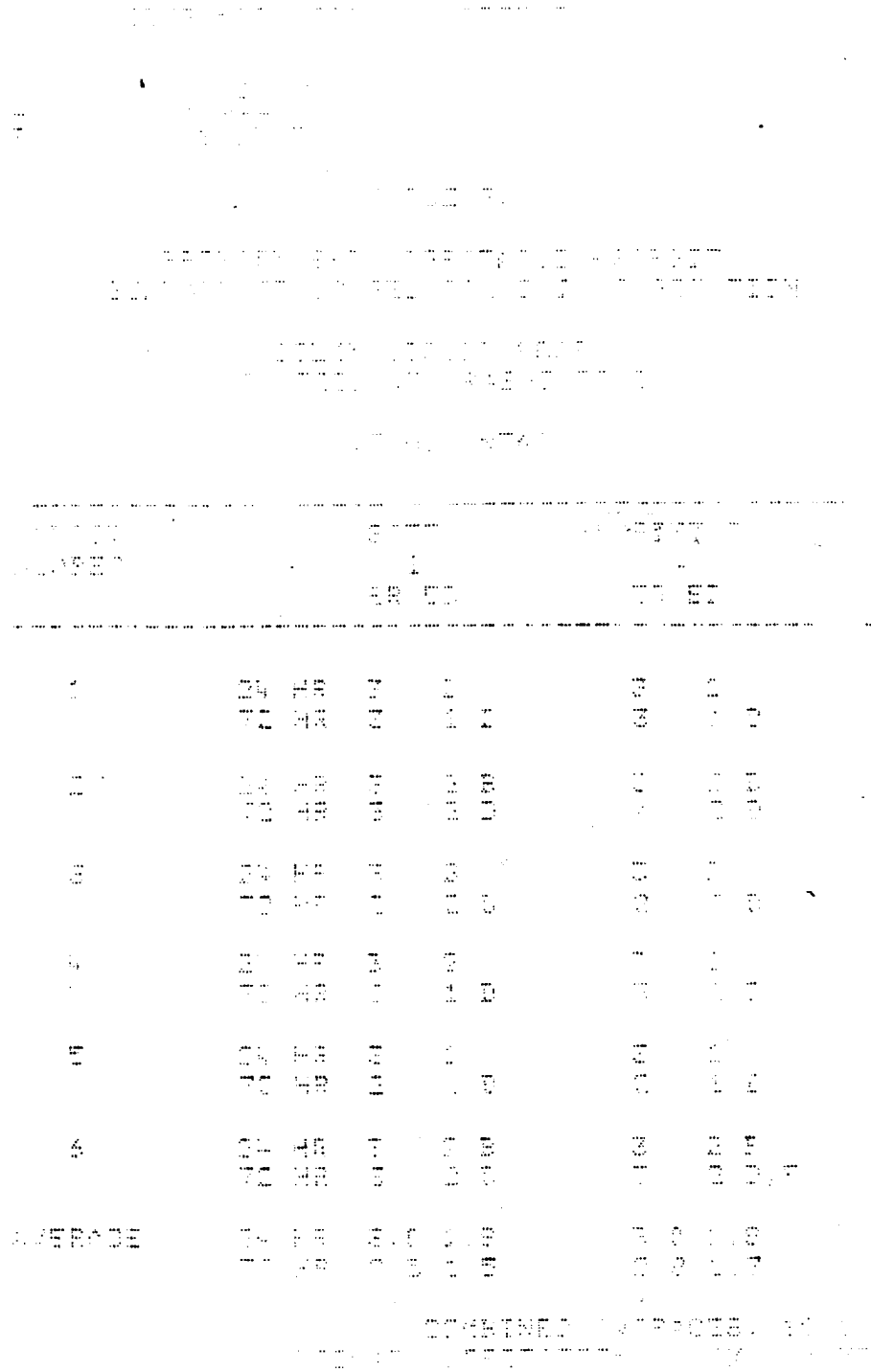
Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required



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Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

FINAL REPORT

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

ATTENTION: Louis J. Nehmsmann, Ph.D.
Manager
Surfactant Research

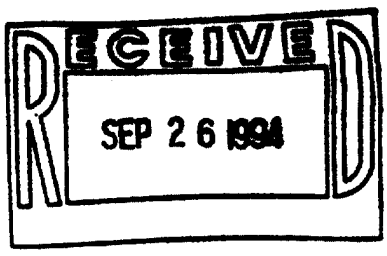
TEST: Primary Dermal Irritation in Rabbits

TEST ARTICLE: Hand Soap, Control No. RAS-3-54-1

EXPERIMENT REFERENCE NO.: 84457 - 1

Steven Nitka
Laboratory Director

Allen L. Palanker
President



Date December 28, 1984
SN/daw

This report details:

a primary dermal irritation study in albino rabbits,

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 3, 1984

and identified as:

Hand Soap, Control No. RAS-3-54-1

was used as indicated in the Final Report Summaries.

Study Interval: December 4, 1984 to December 7, 1984

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue • Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 84457 - 1

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 5, 1984
December 28, 1984

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila Johnson, B.S.	- Laboratory Supervisor
Kerry L. Campbell, B.S.	- Technician
Jamie L. Yorkston, B.A.	- Technician
Deborah A. Worman	- Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director of Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-158
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: December 28, 1984
CLIENT: Alcolac Inc.
STUDY NO.: 84457 - 1
REFERENCE: P.O. No. 23291V
TEST ARTICLE: Hand Soap, Control No. RAS-3-54-1

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 4.95

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions or dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and the latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total possible erythema score = 4	

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score = 4	
Total possible primary irritation score = 8	

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

CONSUMER PRODUCT TESTING CO., INC.

STUDY: 84457-1
CLIENT: ALCOLAC INC.
DATE: 12/04/84

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

HAND SOAP, CONTROL NO. RAS-3-54-1

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	ED		SITE 2 A ER	ED	
1	24 HR	3	2	B	3	2	B
	72 HR	3	2	D,F	3	2	D,F
2	24 HR	3	3		3	3	B*
	72 HR	3	2	D,F	3	2	D*
3	24 HR	3	2	B	3	2	B
	72 HR	3	2	D,F	3	2	D
4	24 HR	3	3		3	3	
	72 HR	2	2		3	2	D,F
5	24 HR	3	2		3	2	
	72 HR	3	1	D	3	1	D
6	24 HR	2	2		2	2	
	72 HR	3	2	D,F	3	3	D,F
AVERAGE	24 HR	2.8	2.3		2.8	2.3	
	72 HR	2.8	1.8		3.0	2.0	

COMBINED AVERAGES: 19.8
PRIMARY IRRITATION INDEX: 4.95

*Severe irritation; not dose related, scored adjacent to it

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

RAW DATA PAGE NO. 7241

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

FINAL REPORT

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

ATTENTION: Louis J. Nehmsmann, Ph.D.
Manager
Surfactant Research

TEST: Primary Dermal Irritation in Rabbits

TEST ARTICLE: Hand Soap, Control No. RAS-3-62-1

EXPERIMENT REFERENCE NO.: 84457 - 3

Steven Nitka
Laboratory Director

Allen L. Palanker
President

Date December 28, 1984
SN/daw

This report details:

a primary dermal irritation study in albino rabbits,

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 3, 1984

and identified as:

Hand Soap, Control No. RAS-3-62-1

was used as indicated in the Final Report Summaries.

Study Interval: December 4, 1984 to December 7, 1984

(201) 575 7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 84457 - 3

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 5, 1984
December 28, 1984

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila Johnson, B.S.	- Laboratory Supervisor
Kerry L. Campbell, B.S.	- Technician
Jamie L. Yorkston, B.A.	- Technician
Deborah A. Worman	- Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director of Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-158
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: December 28, 1984
CLIENT: Alcolac Inc.
STUDY NO.: 84457 - 3
REFERENCE: P.O. No. 23291V
TEST ARTICLE: Hand Soap, Control No. RAS-3-62-1

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 4.00

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions or dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and the latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Summaries of all results are found preceding the text.

Table I

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table [1]
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

CONSUMER PRODUCT TESTING CO., INC.

STUDY: 84457-3
CLIENT: ALCOLAC INC.
DATE: 12/04/84

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

HAND SOAP, CONTROL NO. RAS-3-62-1

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	ED	SITE 2 A ER	ED
1	24 HR	3	3	3	3
	72 HR	2	1 D	2	1 D
2	24 HR	2	1	2	1
	72 HR	1	0	1	0 D
3	24 HR	3	3	3	3
	72 HR	1	1 D	2	2 D,F
4	24 HR	3	2	3	2
	72 HR	1	1 D	2	1 D,F
5	24 HR	3	2	3	2
	72 HR	2	2 D	2	2 D
6	24 HR	3	3	3	3
	72 HR	2	2 D,F	2	2 D,F
AVERAGE	24 HR	2.8	2.3	2.8	2.3
	72 HR	1.5	1.2	1.8	1.3

COMBINED AVERAGES: 16.0
PRIMARY IRRITATION INDEX: 4.00

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

RAW DATA PAGE NO. 7243

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

ATTENTION: Robert Stonier

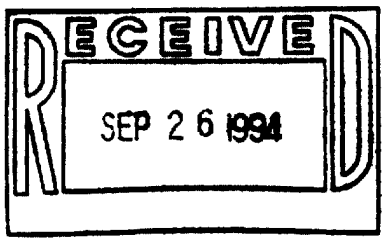
TESTS: Primary Dermal Irritation in Rabbits
Primary Ocular Irritation in Rabbits

TEST ARTICLE: SHAMPOO, RAS-3-295-1

EXPERIMENT REFERENCE NO.: 85552-3

Steven Nitka
Laboratory Director

Allen L. Palanker
President



Date January 8, 1986
SN/mk

This report details:

a primary dermal irritation study, and
a primary ocular irritation study in albino rabbits

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 20, 1985

and identified as:

SHAMPOO, RAS-3-295-1

was used as indicated in the Final Report Summaries.

Study Interval: December 30, 1985 to January 6, 1986

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 85552-3

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 26, 1985
January 2, 1986
January 8, 1986

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila (Johnson) Hamill, B.S.	- Laboratory Supervisor
Joan Breheny, B.S.	- Technician
Philip Lipari, B.S.	- Technician
Kathleen R. (Daly) Paladino	- Animal Care Supervisor
Deborah A. Worman	- Administrative Assistant Member, Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director
Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-3
REFERENCE: P.O.# 24343V
TEST ARTICLE: SHAMPOO, RAS-3-295-1

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour reading were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 4.20

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-3
REFERENCE: P.O.# 24343V
TEST ARTICLE: SHAMPOO, RAS-3-295-1

Primary Ocular Irritation in Rabbits

Method: Six (6) New Zealand white rabbits, free from visible ocular defects, each received a single intraocular application of 0.1 milliliter of the test article. The contralateral eye, remaining untreated, served as a control. The eyes of three (3) animals remained unwashed for 24 hours; the eyes of the remaining three (3) animals were washed out 4 seconds after instillation of the test article. Observations of corneal opacity, iritis, conjunctivitis, and other effects were recorded 24, 48 and 72 hours after treatment, and at 4 and 7 days if irritation persisted. The test article was used as received.

	Draize Scores				
	Hours			Days	
Group	24	48	72	4	7
Unwashed	35.0	16.0	10.0	8.3	4.3
4" Wash	1.3	0.0	0.0	---	---

This test article is a moderate ocular irritant to rabbits under conditions of this test. The wash procedure reduced the severity and duration of the irritation observed.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions of dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and a 4 inch Webril pad. The latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Ocular Irritation in Rabbits

This test was designed to determine the ocular irritation potential of substances in both unwashed and washed eyes of rabbits. The procedure followed was a modification of that described by J.H. Draize.[1]

In the technique of determining toxicity of substances to ocular mucosa, observation of injuries was made on the cornea, iris, and the bulbar and palpebral conjunctivae. Numerical scores were assigned to lesions observed according to the Draize scale. (Refer to appended table.) In this system of scoring, the injuries to the cornea and iris account for approximately 80% of the score; these structures are purposely weighted because of their vital role in vision. The presence of lesions not described in the Draize scale was also noted.

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, were obtained through a suitably licensed dealer. The animals were checked carefully upon receipt for ocular defects, diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition. Any animal exhibiting visible ocular defects or irritation, or in poor condition, was not used in this test.

Animals were acclimated for at least 3 days prior to test initiation. They were housed in galvanized or stainless steel cages and identified through individual markings on the outer ear of each animal, as well as a cage label. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum.

Immediately prior to test initiation, the animals were placed in wooden restrainers. A dose of one-tenth (0.1) of a milliliter of the test article was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test article was dropped. The eyelids were gently held together for 1 second. The contralateral eye, remaining untreated, served as a control.

The eyes of the first three (3) animals remained unwashed for 24 hours, at which time, after reading, any excess test article was gently washed out with lukewarm water. The eyes of the remaining three (3) rabbits were irrigated 4 seconds following instillation of the test article, with sufficient lukewarm water at room temperature to wash out all visible test article. Effects of the washout, either beneficial or detrimental, were noted.

Observations of ocular irritation were recorded 24, 48 and 72 hours following instillation of the test article. Additional readings were made at 4 and 7 days if irritation persisted.

Daily scores were determined for each animal using the weighing system at the top of the data table; then mean daily scores were determined for each of the test groups.

[1] J.H. Draize, "Dermal Toxicity', Appraisal of the Safety Chemical in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975,) pp. 49 - 51.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Primary Ocular Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 4 and 5 respectively. The individual results are presented in Table 6.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

SHAMPOO, RAS-3-295-1

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HRS	2	2	2	2
	72 HRS	3	2 D	3	2 D
2	24 HRS	2	1	2	1
	72 HRS	3	2 D	3	2 D
3	24 HRS	2	1	2	1
	72 HRS	3	2 D,F	3	2 D
4	24 HRS	2	2	2	2
	72 HRS	3	2 D	3	2 D
5	24 HRS	2	2	2	2
	72 HRS	3	1 D	3	1 D
6	24 HRS	2	2	2	2
	72 HRS	3	1	3	1
AVERAGE	24 HRS	2.0	1.7	2.0	1.7
	72 HRS	3.0	1.7	3.0	1.7

COMBINED AVERAGES: 16.9
PRIMARY IRRITATION INDEX: 4.20

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

Table 4

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	Opacity (A)	
	Opacity - degree of density (area which is dense is taken for reading)	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	Area of Cornea Involved (B)	
	One-quarter (or less), but not zero.	1
	Greater than one-quarter, but less than one-half.	2
	Greater than one-half, but less than three-quarters.	3
	Greater than three-quarters, up to whole area.	4
	Score equals A x B x 5 Total maximum = 80	
Iris	Values (A)	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combinations of any thereof), iris still reacting to light.	
	Sluggish reaction is positive.	1
	No reaction to light hemorrhage, gross destruction, (any or all of these).	2
	Score equals A x 5 Total maximum = 10	

Table 4 (cont'd.)

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctivae	Redness (A)	
	Redness (refers to palpebral conjunctivae only). Vessels definitely injected above normal.	1
	More diffuse, crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	Chemosis (B)	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	Discharge (C)	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
	Discharge with moistening of the lids and hairs and considerable area around eye.	3
	Score equals (A + B + C) x 2	Total maximum = 20

Note: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Table 4
(continued)

Scoring Criteria for Eye Reaction - Addendum

Notation	Condition
B	Blanching
BD	Bloody discharge
CE	Corneal Edema
En	Encroachment of Sclera
FVCN	Fibrovascular connective tissue
H	Hair loss around eye
Hm	Hematoma
M	Nodular Mass Subjacent to Meibomian Gland
N	Necrosis
TAC	Test Article Adhering to conjunctivae

Table 5

Eye Irritation
Relative Classification of Test Articles
Based on Grading of Irritation

Rating	Range	Definition
Non-irritating	0.0 - 0.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Practically non-irritating	0.5 - 2.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Minimally irritating	2.5 - 15.0	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating one level.
Mildly irritating	15.0 - 25.0	To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating one level.
Moderately irritating	25.0 - 50.0	To maintain this rating, scores at 7 days must be less than 10 for 3 or more of the animals and mean 7 day scores must be less than 25, otherwise, raise rating one level.
Severely irritating	50.0 - 80.0	To maintain this rating, scores at 7 days must be less than 30 for 3 or more of the animals and mean 7day score must be less than 45, otherwise, raise rating one level.
Extremely irritating	80.0 - 110.0	

TABLE 6

PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

SHAMPOO, RAS-3-295-1

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+			IRIS: A×5(ST2)+		CONJUNCTIVAE: (A+B+C)×2(ST3)=				TOTA SCORE
				UNWASHED							
1	1	1	4	20	1	5	2	3	1	12	37
	2	2	1	10	1	5	3	2	1	12	27
	3	2	1	10	1	5	1	1	1	6	21
	4	1	2	10	0	0	1	1	1	6	16
	7	1	1	5	0	0	1	1	0	4	9
2	1	1	4	20	1	5	2	3	1	12	37
	2	1	1	5	0	0	2	1	1	8	13
	3	1	1	5	0	0	1	1	0	4	9
	4	1	1	5	0	0	1	1	0	4	9
	7	0	0	0	0	0	1	1	0	4	4
3	1	1	4	20	1	5	2	1	0	6	31
	2	0	0	0	0	0	2	1	1	8	8
	3	0	0	0	0	0	0	0	0	0	0
	4	-	-		-		-	-	-		
	7	-	-		-		-	-	-		
AVERAGE	1										35.
	2										16.
	3										10.
	4										8.
	7										4.

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

TABLE 6
(CONTINUED)
PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

SHAMPOO, RAS-3-295-1

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+	IRIS: A×5(ST2)+	CONJUNCTIVAE: (A+B+C)×2(ST3)=	TOTAL SCORE*
		4 SECOND WASH			
4	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
5	1	0 0 0	0 0	0 0 0 0	0
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
6	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
AVERAGE	1				1.
	2				0.
	3				0.
	4				-
	7				-

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

ATTENTION: Robert Stonier

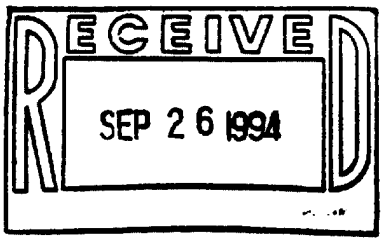
TESTS: **Primary Dermal Irritation in Rabbits**
Primary Ocular Irritation in Rabbits

TEST ARTICLE: HAND SOAP, RAS-3-295-2

EXPERIMENT REFERENCE NO.: 85552-1

Steven Nitka
Laboratory Director

Allen L. Palanker
President



Date January 8, 1986
SN/mk

This report details:

a primary dermal irritation study, and
a primary ocular irritation study in albino rabbits

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 20, 1985

and identified as:

HAND SOAP, RAS-3-295-2

was used as indicated in the Final Report Summaries.

Study Interval: December 30, 1985 to January 6, 1986

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Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 85552-1

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 26, 1985
January 2, 1986
January 8, 1986

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila (Johnson) Hamill, B.S.	- Laboratory Supervisor
Joan Breheny, B.S.	- Technician
Philip Lipari, B.S.	- Technician
Kathleen R. (Daly) Paladino	- Animal Care Supervisor
Deborah A. Worman	- Administrative Assistant Member, Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director
Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-1
REFERENCE: P.O.# 24343V
TEST ARTICLE: HAND SOAP, RAS-3-295-2

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour reading were averaged to determine the primary irritation index. The test article wasused as received.

Primary Irritation Index:* 3.90

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

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Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-1
REFERENCE: P.O.# 24343V
TEST ARTICLE: HAND SOAP, RAS-3-295-2

Primary Ocular Irritation in Rabbits

Method: Six (6) New Zealand white rabbits, free from visible ocular defects, each received a single intraocular application of 0.1 milliliter of the test article. The contralateral eye, remaining untreated, served as a control. The eyes of three (3) animals remained unwashed for 24 hours; the eyes of the remaining three (3) animals were washed out 4 seconds after instillation of the test article. Observations of corneal opacity, iritis, conjunctivitis, and other effects were recorded 24, 48 and 72 hours after treatment, and at 4 and 7 days if irritation persisted. The test article was used as received.

	Draize Scores				
	Hours			Days	
Group	24	48	72	4	7
Unwashed	33.3	37.0	35.7	28.3	19.0
4" Wash	1.3	0.0	0.0	----	----

This test article is a severe ocular irritant to rabbits under conditions of this test. The wash procedure reduced the severity and the duration of the irritation observed.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions of dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and a 4 inch Webril pad. The latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Ocular Irritation in Rabbits

This test was designed to determine the ocular irritation potential of substances in both unwashed and washed eyes of rabbits. The procedure followed was a modification of that described by J.H. Draize.[1]

In the technique of determining toxicity of substances to ocular mucosa, observation of injuries was made on the cornea, iris, and the bulbar and palpebral conjunctivae. Numerical scores were assigned to lesions observed according to the Draize scale. (Refer to appended table.) In this system of scoring, the injuries to the cornea and iris account for approximately 80% of the score; these structures are purposely weighted because of their vital role in vision. The presence of lesions not described in the Draize scale was also noted.

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, were obtained through a suitably licensed dealer. The animals were checked carefully upon receipt for ocular defects, diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition. Any animal exhibiting visible ocular defects or irritation, or in poor condition, was not used in this test.

Animals were acclimated for at least 3 days prior to test initiation. They were housed in galvanized or stainless steel cages and identified through individual markings on the outer ear of each animal, as well as a cage label. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum.

Immediately prior to test initiation, the animals were placed in wooden restrainers. A dose of one-tenth (0.1) of a milliliter of the test article was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test article was dropped. The eyelids were gently held together for 1 second. The contralateral eye, remaining untreated, served as a control.

The eyes of the first three (3) animals remained unwashed for 24 hours, at which time, after reading, any excess test article was gently washed out with lukewarm water. The eyes of the remaining three (3) rabbits were irrigated 4 seconds following instillation of the test article, with sufficient lukewarm water at room temperature to wash out all visible test article. Effects of the washout, either beneficial or detrimental, were noted.

Observations of ocular irritation were recorded 24, 48 and 72 hours following instillation of the test article. Additional readings were made at 4 and 7 days if irritation persisted.

Daily scores were determined for each animal using the weighing system at the top of the data table; then mean daily scores were determined for each of the test groups.

[1] J.H. Draize, "Dermal Toxicity', Appraisal of the Safety Chemical in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975,) pp. 49 - 51.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Primary Ocular Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 4 and 5 respectively. The individual results are presented in Table 6.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

HAND SOAP, RAS-3-295-2

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HRS	2	1	2	1
	72 HRS	3	2 D	3	2 D,F
2	24 HRS	2	1	2	1
	72 HRS	3	1 D	3	1 D
3	24 HRS	2	1	2	1
	72 HRS	3	1 D	3	1 D
4	24 HRS	2	2	2	2
	72 HRS	3	2 D	3	2 D,F
5	24 HRS	2	2	2	2
	72 HRS	3	2 D	3	2 D
6	24 HRS	2	1	2	1
	72 HRS	3	1 D	3	1 D
AVERAGE	24 HRS	2.0	1.3	2.0	1.3
	72 HRS	3.0	1.5	3.0	1.5

COMBINED AVERAGES: 15.6
PRIMARY IRRITATION INDEX: 3.90

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

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Table 4

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	Opacity (A)	
	Opacity - degree of density (area which is dense is taken for reading)	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	Area of Cornea Involved (B)	
	One-quarter (or less), but not zero.	1
	Greater than one-quarter, but less than one-half.	2
	Greater than one-half, but less than three-quarters.	3
	Greater than three-quarters, up to whole area.	4
	Score equals A x B x 5 Total maximum = 80	
Iris	Values (A)	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combinations of any thereof), iris still reacting to light.	
	Sluggish reaction is positive.	1
	No reaction to light hemorrhage, gross destruction, (any or all of these).	2
	Score equals A x 5 Total maximum = 10	

Table 4 (cont'd.)

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctivae	**Redness (A)**	
	Redness (refers to palpebral conjunctivae only). Vessels definitely injected above normal.	1
	More diffuse, crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	Chemosis (B)	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	Discharge (C)	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
	Discharge with moistening of the lids and hairs and considerable area around eye.	3
	Score equals (A + B + C) x 2	Total maximum = 20

Note: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Table 4
(continued)

Scoring Criteria for Eye Reaction - Addendum

Notation	Condition
B	Blanching
BD	Bloody discharge
CE	Corneal Edema
En	Encroachment of Sclera
FVCN	Fibrovascular connective tissue
H	Hair loss around eye
Hm	Hematoma
M	Nodular Mass Subjacent to Meibomian Gland
N	Necrosis
TAC	Test Article Adhering to conjunctivae

Table 5

Eye Irritation
Relative Classification of Test Articles
Based on Grading of Irritation

Rating	Range	Definition
Non-irritating	0.0 - 0.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Practically non-irritating	0.5 - 2.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Minimally irritating	2.5 - 15.0	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating one level.
Mildly irritating	15.0 - 25.0	To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating one level.
Moderately irritating	25.0 - 50.0	To maintain this rating, scores at 7 days must be less than 10 for 3 or more of the animals and mean 7 day scores must be less than 25, otherwise, raise rating one level.
Severely irritating	50.0 - 80.0	To maintain this rating, scores at 7 days must be less than 30 for 3 or more of the animals and mean 7day score must be less than 45, otherwise, raise rating one level.
Extremely irritating	80.0 - 110.0	

TABLE 6

PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

HAND SOAP, RAS-3-295-2

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+	IRIS: A×5(ST2)+	CONJUNCTIVAE: (A+B+C)×2(ST3)=	TOTAL SCORE*
		UNWASHED			
1	1	1 4 20	1 5	2 2 1 10	35
	2	2 2 20	1 5	3 3 2 16	41
	3	2 3 30	1 5	2 2 1 10	45
	4	4 1 20 FVCN	0 0	1 1 0 4	24
	7	4 1 20 FVCN	0 0	1 0 0 2	22
2	1	1 3 15	1 5	2 2 1 10	30
	2	2 1 10	1 5	3 2 2 14	29
	3	2 1 10	1 5	2 2 1 10	25
	4	4 1 20 FVCN	0 0	1 2 0 6	26
	7	0 0 0	0 0	1 0 0 2	2
3	1	1 4 20	1 5	2 2 1 10	35
	2	1 4 20	1 5	3 3 2 16	41
	3	1 4 20	1 5	3 2 1 12	37
	4	4 1 20 FVCN	1 5	2 2 1 10	35
	7	4 1 20 FVCN	1 5	2 2 0 8	33
AVERAGE	1				33.
	2				37.
	3				35.
	4				28.
	7				19.

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

TABLE 6
(CONTINUED)
PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

HAND SOAP, RAS-3-295-2

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+	IRIS: A×5(ST2)+	CONJUNCTIVAE: (A+B+C)×2(ST3)=	TOTAL SCORE
		4 SECOND WASH			
4	1	0 0 0	0 0	0 0 0 0	0
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
5	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
6	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
AVERAGE	1				1.
	2				0.
	3				0.
	4				-
	7				-

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

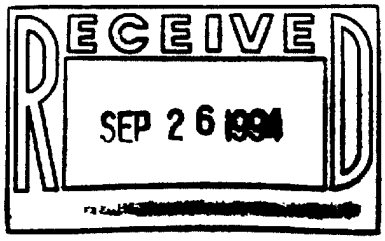
ATTENTION: Robert Stonier

TESTS: Primary Dermal Irritation in Rabbits
Primary Ocular Irritation in Rabbits

TEST ARTICLE: SURFACTANT, RAS-3-295-3

EXPERIMENT REFERENCE NO.: 85552-4

Steven Nitka
Laboratory Director



Allen L. Palanker
President

Date January 8, 1986
SN/mk

This report details:

a primary dermal irritation study, and
a primary ocular irritation study in albino rabbits

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 20, 1985

and identified as:

SURFACTANT, RAS-3-295-3

was used as indicated in the Final Report Summaries.

Study Interval: December 30, 1985 to January 6, 1986

(201) 575-7688
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Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 85552-4

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 26, 1985
January 2, 1986
January 8, 1986

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila (Johnson) Hamill, B.S.	- Laboratory Supervisor
Joan Breheny, B.S.	- Technician
Philip Lipari, B.S.	- Technician
Kathleen R. (Daly) Paladino	- Animal Care Supervisor
Deborah A. Worman	- Administrative Assistant Member, Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk, B.S.
Director
Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac inc.
STUDY NO.: 85552-4
REFERENCE: P.O.# 24343V
TEST ARTICLE: SURFACTANT, RAS-3-295-3

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour reading were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 4.40

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

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(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8,1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-4
REFERENCE: P.O.# 24343V
TEST ARTICLE: SURFACTANT, RAS-3-295-3

Primary Ocular Irritation in Rabbits

Method: Six (6) New Zealand white rabbits, free from visible ocular defects, each received a single intraocular application of 0.1 milliliter of the test article. The contralateral eye, remaining untreated, served as a control. The eyes of three (3) animals remained unwashed for 24 hours; the eyes of the remaining three (3) animals were washed out 4 seconds after instillation of the test article. Observations of corneal opacity, iritis, conjunctivitis, and other effects were recorded 24, 48 and 72 hours after treatment, and at 4 and 7 days if irritation persisted. The test article was used as received.

	Draize Scores				
	Hours			Days	
Group	24	48	72	4	7
Unwashed	36.3	23.7	15.7	6.0	0.7
4" Wash	2.0	3.3	0.7	0.7	0.0

This test article is a moderate ocular irritant to rabbits under conditions of this test. The wash procedure reduced the severity and duration of the irritation observed.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions of dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and a 4 inch Webril pad. The latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Ocular Irritation in Rabbits

This test was designed to determine the ocular irritation potential of substances in both unwashed and washed eyes of rabbits. The procedure followed was a modification of that described by J.H. Draize.[1]

In the technique of determining toxicity of substances to ocular mucosa, observation of injuries was made on the cornea, iris, and the bulbar and palpebral conjunctivae. Numerical scores were assigned to lesions observed according to the Draize scale. (Refer to appended table.) In this system of scoring, the injuries to the cornea and iris account for approximately 80% of the score; these structures are purposely weighted because of their vital role in vision. The presence of lesions not described in the Draize scale was also noted.

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, were obtained through a suitably licensed dealer. The animals were checked carefully upon receipt for ocular defects, diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition. Any animal exhibiting visible ocular defects or irritation, or in poor condition, was not used in this test.

Animals were acclimated for at least 3 days prior to test initiation. They were housed in galvanized or stainless steel cages and identified through individual markings on the outer ear of each animal, as well as a cage label. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum.

Immediately prior to test initiation, the animals were placed in wooden restrainers. A dose of one-tenth (0.1) of a milliliter of the test article was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test article was dropped. The eyelids were gently held together for 1 second. The contralateral eye, remaining untreated, served as a control.

The eyes of the first three (3) animals remained unwashed for 24 hours, at which time, after reading, any excess test article was gently washed out with lukewarm water. The eyes of the remaining three (3) rabbits were irrigated 4 seconds following instillation of the test article, with sufficient lukewarm water at room temperature to wash out all visible test article. Effects of the washout, either beneficial or detrimental, were noted.

Observations of ocular irritation were recorded 24, 48 and 72 hours following instillation of the test article. Additional readings were made at 4 and 7 days if irritation persisted.

Daily scores were determined for each animal using the weighing system at the top of the data table; then mean daily scores were determined for each of the test groups.

[1] J.H. Draize, "Dermal Toxicity', Appraisal of the Safety Chemical in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975,) pp. 49 - 51.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Primary Ocular Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 4 and 5 respectively. The individual results are presented in Table 6.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

SURFACTANT, RAS-3-295-3

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HRS	2	2	2	2
	72 HRS	3	2 D	3	2 D,F
2	24 HRS	2	2 B	2	2 B
	72 HRS	3	2 D	3	2 D
3	24 HRS	2	2 B	2	2 B
	72 HRS	3	2 D,F	3	2 D,F
4	24 HRS	2	2	2	2
	72 HRS	3	2 D,F	3	2 D
5	24 HRS	2	1	2	2
	72 HRS	3	1 D	3	2 D
6	24 HRS	2	2 B	2	2
	72 HRS	3	2 D	3	2 D
AVERAGE	24 HRS	2.0	1.8	2.0	2.0
	72 HRS	3.0	1.8	3.0	2.0

COMBINED AVERAGES: 17.6
PRIMARY IRRITATION INDEX: 4.40

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

RAW DATA PAGE NO. 7956

Table 4

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	Opacity (A)	
	Opacity - degree of density (area which is dense is taken for reading)	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	Area of Cornea Involved (B)	
	One-quarter (or less), but not zero.	1
	Greater than one-quarter, but less than one-half.	2
	Greater than one-half, but less than three-quarters.	3
	Greater than three-quarters, up to whole area.	4
	Score equals A x B x 5	Total maximum = 80
Iris	Values (A)	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combinations of any thereof), iris still reacting to light.	
	Sluggish reaction is positive.	1
	No reaction to light hemorrhage, gross destruction, (any or all of these).	2
	Score equals A x 5	Total maximum = 10

Table 4 (cont'd.)

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctivae	Redness (A)	
	Redness (refers to palpebral conjunctivae only). Vessels definitely injected above normal.	1
	More diffuse, crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	Chemosis (B)	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	Discharge (C)	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
	Discharge with moistening of the lids and hairs and considerable area around eye.	3
	Score equals (A + B + C) x 2	Total maximum = 20

Note: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Table 4

Scoring Criteria for Eye Reaction - Addendum

Notation	Condition
B	Blanching
BD	Bloody discharge
CE	Corneal Edema
En	Encroachment of Sclera
FVCN	Fibrovascular connective tissue
H	Hair loss around eye
Hm	Hematoma
M	Nodular Mass Subjacent to Meibomian Gland
N	Necrosis
TAC	Test Article Adhering to conjunctivae

Table 5

Eye Irritation
Relative Classification of Test Articles
Based on Grading of Irritation

Rating	Range	Definition
Non-irritating	0.0 - 0.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Practically non-irritating	0.5 - 2.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Minimally irritating	2.5 - 15.0	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating one level.
Mildly irritating	15.0 - 25.0	To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating one level.
Moderately irritating	25.0 - 50.0	To maintain this rating, scores at 7 days must be less than 10 for 3 or more of the animals and mean 7 day scores must be less than 25, otherwise, raise rating one level.
Severely irritating	50.0 - 80.0	To maintain this rating, scores at 7 days must be less than 30 for 3 or more of the animals and mean 7day score must be less than 45, otherwise, raise rating one level.
Extremely irritating	80.0 - 110.0	

TABLE 6

PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

SURFACTANT, RAS-3-295-3

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+	IRIS: A×5(ST2)+	CONJUNCTIVAE: (A+B+C)×2(ST3)=	TOTAL SCORES
		UNWASHED			
1	1	1 4 20	1 5	2 3 1 12	37
	2	1 4 20	1 5	3 2 1 12	37
	3	1 4 20	0 0	2 1 1 8	28
	4	1 2 10	0 0	1 1 0 4	14
	7	0 0 0	0 0	1 0 0 2	2
2	1	1 4 20	1 5	2 3 1 12	37
	2	1 1 5	0 0	3 2 1 12	17
	3	0 0 0	0 0	1 0 0 2	2
	4	0 0 0	0 0	1 0 0 2	2
	7	0 0 0	0 0	0 0 0 0	0
3	1	1 4 20	1 5	2 2 1 10	35
	2	1 1 5	0 0	3 2 1 12	17
	3	1 3 15	0 0	1 0 0 2	17
	4	0 0 0	0 0	1 0 0 2	2
	7	0 0 0	0 0	0 0 0 0	0
AVERAGE	1				36.
	2				23.
	3				15.
	4				6.
	7				0.

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

STUDY: [illegible]
CLIENT: HELENE CURTIS INC.
DATE: 12/30/85

TABLE 8
(CONTINUED)
PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

SURFACTANT, RAS-3-295-3

8 EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+			IRIS: A×5(ST2)+		CONJUNCTIVAE: (A+B+C)×2(ST3)=			TOTAL SCORE
				4 SECOND WASH						
4	1	0	0	0	0	0	1	0	0	2
	2	0	0	0	0	0	2	1	1	8
	3	0	0	0	0	0	1	0	0	2
	4	0	0	0	0	0	1	0	0	2
	7	0	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	1	0	0	2
	2	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0
	4	-	-		-		-	-	-	
	7	-	-		-		-	-	-	
6	1	0	0	0	0	0	1	0	0	2
	2	0	0	0	0	0	1	0	0	2
	3	0	0	0	0	0	0	0	0	0
	4	-	-		-		-	-	-	
	7	-	-		-		-	-	-	
AVERAGE	1									2.
	2									1.
	3									0.
	4									
	7									0.

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

Consumer Product Testing

Company Incorporated

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Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

Contains No CBI

CLIENT: Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

ATTENTION: Robert Stonier

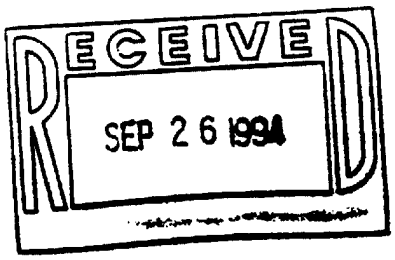
TESTS: Primary Dermal Irritation in Rabbits
Primary Ocular Irritation in Rabbits

TEST ARTICLE: HAND SOAP, RAS-3-295-5

EXPERIMENT REFERENCE NO.: 85552-2

Steven Nitka
Laboratory Director

Allen L. Palanker
President



Date January 8, 1986
SN/mk

This report details:

a primary dermal irritation study, and
a primary ocular irritation study in albino rabbits

performed at the behest of:

Alcolac Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

The test article(s), supplied by:

Alcolac Inc.

received on:

December 20, 1985

and identified as:

HAND SOAP, RAS-3-295-5

was used as indicated in the Final Report Summaries.

Study Interval: December 30, 1985 to January 6, 1985

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Consumer Product Testing

Company Incorporated

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1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

QUALITY ASSURANCE UNIT SUMMARY

Study No.: 85552-2

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of nonclinical laboratory studies as set forth in the Good Laboratory Practice regulations (21 CFR 58). The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected every three months; and studies lasting less than six months are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to management and Study Director. All materials and data pertinent to this study will be stored in the Archives Facility.

Date(s) of inspections: December 26, 1985
January 2, 1986
January 8, 1986

Professional personnel involved:

Steven Nitka, B.S.	- Laboratory Director (Study Director)
Sheila (Johnson) Hamill, B.S.	- Laboratory Supervisor
Joan Breheny, B.S.	- Technician
Philip Lipari, B.S.	- Technician
Kathleen R. (Daly) Paladino	- Animal Care Supervisor
Deborah A. Worman	- Administrative Assistant Member, Quality Assurance Unit

The following has been assured by signing below that this study has been performed in accordance with standard operating procedures and the Good Laboratory Practice regulations.

Barbara A. Adamczyk

Barbara A. Adamczyk, B.S.
Director
Quality Assurance and Office Services

(201) 575-7688
(201) 575-7689

Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue ● Fairfield, New Jersey 07006

Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-2
REFERENCE: P.O.# 24343V
TEST ARTICLE: HAND SOAP, RAS-3-295-5

Primary Dermal Irritation in Rabbits

Method: Six (6) New Zealand white rabbits each received a single dermal application of 0.5 milliliter of the test article on two test sites, one abraded and one intact. The test sites were occluded for 24 hours and were observed individually for erythema, edema, and other effects 24 and 72 hours after application. Mean scores from the 24 and 72 hour reading were averaged to determine the primary irritation index. The test article was used as received.

Primary Irritation Index:* 3.70

This test article is not a primary dermal irritant to rabbits under conditions of this test.

*Refer to Table 2 for specific evaluation.

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Consumer Product Testing

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Final Report Summary

DATE: January 8, 1986
CLIENT: Alcolac Inc.
STUDY NO.: 85552-2
REFERENCE: P.O.# 24343V
TEST ARTICLE: HAND SOAP, RAS-3-295-5

Primary Ocular Irritation in Rabbits

Method: Six (6) New Zealand white rabbits, free from visible ocular defects, each received a single intraocular application of 0.1 milliliter of the test article. The contralateral eye, remaining untreated, served as a control. The eyes of three (3) animals remained unwashed for 24 hours; the eyes of the remaining three (3) animals were washed out 4 seconds after instillation of the test article. Observations of corneal opacity, iritis, conjunctivitis, and other effects were recorded 24, 48 and 72 hours after treatment, and at 4 and 7 days if irritation persisted. The test article was used as received.

	Draize Scores				
	Hours			Days	
Group	24	48	72	4	7
Unwashed	20.3	9.0	8.7	1.3	0.7
4" Wash	0.7	0.7	0.0	---	---

This test article is a moderate ocular irritant to rabbits under conditions of this test. The wash procedure reduced the severity and duration of the irritation observed.

Primary Dermal Irritation in Rabbits

This test was designed to identify substances which are primary irritants to rabbit skin. The procedure followed was a modification of that described by J.H. Draize.[1]

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, sex unspecified, were obtained from a suitably licensed dealer. Animals were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition.

Animals were acclimated at least 4 days prior to test initiation. They were housed in galvanized or stainless steel cages, in a temperature controlled room with a 12 hour light/dark cycle. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum. Animals were identified through individual markings on the outer ear of each animal, as well as a cage label.

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition, and particularly animals with skin eruptions of dermal lesions, were not used. Animals were prepared for testing by close-clipping the skin of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using a small animal clipper equipped with a #40 (surgical) head.

Immediately prior to test initiation, the animals were placed in wooden restrainers. Two (2) test sites, each 2.5 centimeters square, were chosen on opposite sides of the vertebral column. The test site on the left side of the animal remained intact; the test site on the right was further prepared by abrading with a sterile 22 gauge hypodermic needle. The abrasions were longitudinal epidermal incisions, sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma, i.e., to cause bleeding.

A single application of one-half (0.5) of a milliliter of the test article was made to each test site. The test article was then covered with a 2.5 cm^2 surgical gauze pad, and a 4 inch Webril pad. The latter held in place with adhesive tape.

After both test sites were treated, the entire trunk of each animal was encased in an impermeable occlusive wrapping fixed in place with adhesive tape. This aided in maintaining the test article and patches in position and prevented the evaporation of possible volatile components of the test article.

The wrapping and test article were removed 24 hours following application. Remaining test article was gently wiped from the skin, and each test site was individually examined and scored at 24 and 72 hours for erythema and edema using the Draize skin scoring scale. (Refer to appended table.) The presence of effects not listed in the scoring scale was also noted.

Following the 72 hour reading, the mean scores for 24 and 72 hour gradings were averaged to determine the primary skin irritation index. A score of 5.0 or more indicates a primary dermal irritant.

[1] J.H. Draize, "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975), p. 47.

Primary Ocular Irritation in Rabbits

This test was designed to determine the ocular irritation potential of substances in both unwashed and washed eyes of rabbits. The procedure followed was a modification of that described by J.H. Draize.[1]

In the technique of determining toxicity of substances to ocular mucosa, observation of injuries was made on the cornea, iris, and the bulbar and palpebral conjunctivae. Numerical scores were assigned to lesions observed according to the Draize scale. (Refer to appended table.) In this system of scoring, the injuries to the cornea and iris account for approximately 80% of the score; these structures are purposely weighted because of their vital role in vision. The presence of lesions not described in the Draize scale was also noted.

Six (6) New Zealand white rabbits, weighing approximately 2 kilograms and about 3 months of age, were obtained through a suitably licensed dealer. The animals were checked carefully upon receipt for ocular defects, diarrhea and dehydration, respiratory difficulties, postural deficiencies, and general condition. Any animal exhibiting visible ocular defects or irritation, or in poor condition, was not used in this test.

Animals were acclimated for at least 3 days prior to test initiation. They were housed in galvanized or stainless steel cages and identified through individual markings on the outer ear of each animal, as well as a cage label. Diet consisted of a growth and maintenance ration from a commercial producer, as well as water, ad libitum.

Immediately prior to test initiation, the animals were placed in wooden restrainers. A dose of one-tenth (0.1) of a milliliter of the test article was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test article was dropped. The eyelids were gently held together for 1 second. The contralateral eye, remaining untreated, served as a control.

The eyes of the first three (3) animals remained unwashed for 24 hours, at which time, after reading, any excess test article was gently washed out with lukewarm water. The eyes of the remaining three (3) rabbits were irrigated 4 seconds following instillation of the test article, with sufficient lukewarm water at room temperature to wash out all visible test article. Effects of the washout, either beneficial or detrimental, were noted.

Observations of ocular irritation were recorded 24, 48 and 72 hours following instillation of the test article. Additional readings were made at 4 and 7 days if irritation persisted.

Daily scores were determined for each animal using the weighing system at the top of the data table; then mean daily scores were determined for each of the test groups.

[1] J.H. Draize, "Dermal Toxicity', Appraisal of the Safety Chemical in Foods, Drugs and Cosmetics (The Association of Food and Drug Officials of the United States, 1975,) pp. 49 - 51.

Primary Dermal Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Primary Ocular Irritation in Rabbits

The scoring and irritant classification scales used are presented in Tables 4 and 5 respectively. The individual results are presented in Table 6.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

Erythema Formation	
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
B	Blanching	Loss of color; skin is left pale, grey-white
	Blister	See vesicle.
Bu	Bulla	A vesicle greater than 1 cm in diameter.
C	Crust	Scab. Dried exudate on the surface of a lesion.
D	Dry	Skin feels dry to the touch (dehydrated).
Dy	Dye	Dye from the test article remains after excess removed. (Noted because it may cause difficulty in scoring.)
F	Fissure	A linear cleavage into the epidermis, or through epidermis into dermis. May be single or multiple tiny cracks, or large clefts.
P	Pustule	Small circumscribed elevation of skin filled with pus, usually yellow.
R	Red ring	Red ring formed around test site where blanching and possible necrosis/irreversible damage observed at 24 and/or 72 hours. Ring forms between 5 to 7 days, indicative of irreversible damage.
	Scab	See crust.
S	Scale	Accumulation of loose fragments of horny layer of skin (stratum corneum). Peeling. Only uppermost layer involved.

Table 1
(continued)

Scoring Criteria for Skin Reactions - Addendum

Notation	Lesion/Condition	Description
Sc	Scar	An area of fibrous tissue that has replaced damaged dermis or subcutaneous tissues. Found after a crust has sloughed off. Usually does not develop with 72 hours.
U	Ulcer	A break in the continuity of epidermis with exposure of the underlying dermis. An 'open sore'. If test-induced, indicates a 'corrosive' compound. Score test site as appears, note U.
V	Vesicle	Sharply circumscribed elevation of skin filled with clear, free fluid, up to 1 cm in diameter.

Table 2

Scale of Interpreting
Primary Dermal Irritation Scores
(Draize-Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning label must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label may be considered
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

TABLE 3

PRIMARY SKIN IRRITATION - RABBIT
SUMMARY OF SCORES FOR SKIN IRRITATION

HAND SOAP, RAS-3-295-5

0.5 ML, NEAT

RABBIT NUMBER	DAY	SITE 1 I ER	SITE 1 I ED	SITE 2 A ER	SITE 2 A ED
1	24 HRS	3	2	3	2
	72 HRS	3	2 D	3	2 D
2	24 HRS	2	2	2	2
	72 HRS	3	1 D	3	1 D
3	24 HRS	2	1	2	1
	72 HRS	2	1	2	1
4	24 HRS	2	1	2	1
	72 HRS	2	1	2	1
5	24 HRS	2	1	2	1
	72 HRS	3	2	3	2
6	24 HRS	2	1	2	2
	72 HRS	2	1	2	1
AVERAGE	24 HRS	2.2	1.3	2.2	1.5
	72 HRS	2.5	1.3	2.5	1.3

COMBINED AVERAGES: 14.8
PRIMARY IRRITATION INDEX: 3.70

I=INTACT, A=ABRADED, ER=ERYTHEMA, ED=EDEMA

Table 4

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	Opacity (A)	
	Opacity - degree of density (area which is dense is taken for reading)	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	Area of Cornea Involved (B)	
	One-quarter (or less), but not zero.	1
	Greater than one-quarter, but less than one-half.	2
	Greater than one-half, but less than three-quarters.	3
	Greater than three-quarters, up to whole area.	4
	Score equals A x B x 5	Total maximum = 80
Iris	Values (A)	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combinations of any thereof), iris still reacting to light.	
	Sluggish reaction is positive.	1
	No reaction to light hemorrhage, gross destruction, (any or all of these).	2
	Score equals A x 5	Total maximum = 10

Table 4 (cont'd.)

Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctivae	**Redness (A)**	
	Redness (refers to palpebral conjunctivae only).	
	Vessels definitely injected above normal.	1
	More diffuse, crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	Chemosis (B)	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	Discharge (C)	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
	Discharge with moistening of the lids and hairs and considerable area around eye.	3
	Score equals (A + B + C) x 2	Total maximum = 20

Note: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Table 4
(continued)

Scoring Criteria for Eye Reaction - Addendum

Notation	Condition
B	Blanching
BD	Bloody discharge
CE	Corneal Edema
En	Encroachment of Sclera
FVCN	Fibrovascular connective tissue
H	Hair loss around eye
Hm	Hematoma
M	Nodular Mass Subjacent to Meibomian Gland
N	Necrosis
TAC	Test Article Adhering to conjunctivae

Table 5

Eye Irritation
Relative Classification of Test Articles
Based on Grading of Irritation

Rating	Range	Definition
Non-irritating	0.0 - 0.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Practically non-irritating	0.5 - 2.5	To maintain this rating, all scores at the 48 hour reading must be zero; otherwise, increase rating one level.
Minimally irritating	2.5 - 15.0	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating one level.
Mildly irritating	15.0 - 25.0	To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating one level.
Moderately irritating	25.0 - 50.0	To maintain this rating, scores at 7 days must be less than 10 for 3 or more of the animals and mean 7 day scores must be less than 25, otherwise, raise rating one level.
Severely irritating	50.0 - 80.0	To maintain this rating, scores at 7 days must be less than 30 for 3 or more of the animals and mean 7day score must be less than 45, otherwise, raise rating one level.
Extremely irritating	80.0 - 110.0	

TABLE 6

PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

HAND SOAP, RAS-3-295-5

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+			IRIS: A×5(ST2)+		CONJUNCTIVAE: (A+B+C)×2(ST3)=				TOTAL SCORE
				UNWASHED							
1	1	0	0	0	0	0	1	1	1	6	6
	2	0	0	0	0	0	1	1	0	4	4
	3	0	0	0	0	0	1	0	0	2	2
	4	0	0	0	0	0	0	0	0	0	0
	7	-	-		-		-	-	-		
2	1	1	4	20	1	5	2	2	1	10	35
	2	1	1	5	0	0	2	2	2	12	17
	3	1	4	20	0	0	1	0	0	2	22
	4	0	0	0	0	0	1	0	0	2	2
	7	0	0	0	0	0	1	0	0	2	2
3	1	1	1	5	1	5	2	2	1	10	20
	2	0	0	0	0	0	1	1	1	6	6
	3	0	0	0	0	0	1	0	0	2	2
	4	0	0	0	0	0	1	0	0	2	2
	7	0	0	0	0	0	0	0	0	0	0
AVERAGE	1										20.
	2										9.
	3										8.
	4										1.
	7										0.

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

TABLE 6
(CONTINUED)
PRIMARY EYE IRRITATION - RABBITS
SUMMARY OF EYE IRRITATION

HAND SOAP, RAS-3-295-5

R EYE 0.1 ML, NEAT

RABBIT NUMBER	DAY	CORNEA: A×B×5(ST1)+	IRIS: A×5(ST2)+	CONJUNCTIVAE: (A+B+C)×2(ST3)=	TOTAL SCORES
		4 SECOND WASH			
4	1	0 0 0	0 0	0 0 0 0	0
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
5	1	0 0 0	0 0	1 0 0 2	2
	2	0 0 0	0 0	1 0 0 2	2
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
6	1	0 0 0	0 0	0 0 0 0	0
	2	0 0 0	0 0	0 0 0 0	0
	3	0 0 0	0 0	0 0 0 0	0
	4	- -	-	- - -	
	7	- -	-	- - -	
AVERAGE	1				0.
	2				0.
	3				0.
	4				-
	7				-

*TOTAL SCORE POSSIBLE/ANIMAL/OBSERVATION=110

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

James E. Blum
Product Safety Compliance Manager
Rhône-Poulenc Inc.
Specialty Chemicals Divisions
CN 7500
Cranbury, New Jersey 08512-7500

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 30 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

13224A

EPA INFORMATION REQUESTS

Document ID: 8EHQ-1094-13224

EPA requests:

1. [ ] No additional information at this time.

2. [ ] Additional information or clarification on

3. [ ] A full copy of the final report (including the actual experimental protocol, applicable results of gross or histopathologic examinations, data, results of any statistical analyses, etc.) from each study mentioned in your submission.

4. [✓] A description of all voluntary actions taken by your company in response to the findings indicated in your submission.

5. [ ] A complete copy of the current and/or revised Material Safety Data Sheets and labels for the following chemical(s) listed in your submission:

_____ _____

_____ _____

_____ _____

6. [ ]

Please direct questions regarding these requests to Mr. Terry O'Bryan (202-260-3483) or Mr. John Myers (202-260-3543) of the OPPT Risk Analysis Branch.

Triage of 8(e) Submissions

Date sent to triage: _____

NON-CAP CAP

Submission number: 13224A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 **pages** 1-3 **pages** 1-3

Notes:

Contractor reviewer : LPS **Date:** 12/13/94.

CECATS\TRIAGE TRACKING DBASE ...

CECATS DATA:
Submission # 8EHQ- 1094 - 13224 SEQ. A

TYPE: (INT.) SUPP FLWP

SUBMITTER NAME: Rhone - Poulenc Inc.

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL. ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/12/94 [illegible] DATE: 10/18/94 CSRAD DATE: 11/16/94

CHEMICAL NAME:
Alconate L-3
Sipoteric 1398
AKypo RLM-45N

CAS#	
68815-56-5	Surfactant, RAS 3-295-123 un
68650-39-5	Surfactant, RAB-9-278 unkno
50546-32-2	Silky Liquid Soap "
2235-54-3	Hand Soap "
	33939-64-9

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 (02) 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
(0243)	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
(0248)	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA: CAS SR

NON-CBI INVENTORY: (YES) NO (IN TRAINING)

ONGOING REVIEW: YES (DROP/REFER) NO (CONTINUE) REFER

SPECIES: RBT

TOXICOLOGICAL CONCERN:
(LOW) Dermal Irritation, Ocular Irritation
(MED) Dermal Irritation, Ocular Irritation
HIGH

USE: hand soap, shampoo; RAD Surfactant

PRODUCTION:

[illegible]

13224A

M

15% Alconate L-3
Dermal irritation is of medium concern based on well-defined erythema and slight to moderate edema in 6 rabbits, which lessened in severity by 72 hours.

15% Sipoteric 1398
Dermal irritation is of medium concern based on persistent moderate to severe erythema, and slight to moderate edema in rabbits. Fissures were also noted in 3/6 rabbits.

15% Sipoteric COB

Dermal irritation is of medium concern based on persistent moderate to severe erythema, and slight to moderate edema in rabbits. Fissures were also noted in 1/6 rabbits.

Akypo RLM-45N (15%)
Dermal irritation is of medium concern based on reversible moderate to severe erythema, and slight edema in 6 rabbits.

Surfactant, RAS-3-295-4
Dermal irritation is of medium concern based on persistent moderate to severe erythema, and slight to moderate edema in rabbits. Blanching was also noted in 6/6 rabbits.

Ocular irritation is of medium concern based on corneal opacity, iritis, and conjunctival irritation in 3 rabbits, which lessened within 7 days.

Surfactant, RAB-9-278
Ocular irritation is of medium concern based on corneal opacity, iritis, and conjunctival irritation in 3 rabbits, which persisted through day 7. Fibrovascular connective tissue was also noted in 2/3 rabbits on day 7.

Silky Liquid Soap, RAS-3-23-2
Dermal irritation is of medium concern based on persistent moderate to severe erythema, and slight to moderate edema in 6 rabbits. Blanching was also noted in 3/6 rabbits.

Hand Soap, RAS-3-54-1
Dermal irritation is of medium concern based on persistent moderate to severe erythema, and slight to moderate edema in 6 rabbits. Blanching and/or fissures were observed in 4/6 rabbits.

Hand Soap, RAS-3-62-1
Dermal irritation is of medium concern based on moderate to severe erythema, and slight to severe edema in 6 rabbits, which lessened in severity over 72 hours. Fissures were also noted in 1/6 rabbits.

Shampoo, RAS-3-295-1
Dermal irritation is of medium concern based on persistent moderate to severe erythema, and slight edema in 6 rabbits. Fissures were also noted in 1/6 rabbits.

Ocular irritation is of medium concern based on corneal opacity, iritis and conjunctival irritation in 3 rabbits, which lessened by day 7.

Hand Soap, RAS-3-295-2
Dermal irritation is of medium concern based on persistent moderate to severe erythema, and very slight to slight edema in 6 rabbits.

Ocular irritation is of medium concern based on corneal opacity, iritis and conjunctival irritation in 3 rabbits, which persisted through day 7. Fibrovascular connective tissue was also noted in 3/3 rabbits.

Surfactant, RAS-3-295-3
Dermal irritation is of medium concern based on persistent moderate to severe erythema, and slight edema in 6 rabbits. Blanching and/or fissures were also noted in 4/6 rabbits.

Ocular irritation is of medium concern based on reversible corneal opacity, iritis and conjunctival irritation in 3 rabbits.

Hand Soap, RAS-3-295-5
Dermal irritation is of medium concern based on persistent moderate to severe erythema, and very slight to slight edema in 6 rabbits.

L

Surfactant, RAB-9-278
Dermal irritation is of low concern based on very slight to well-defined erythema, and very slight to slight edema in 6 rabbits, which lessened by 72 hours.

Hand Soap, RAS-3-295-5
Ocular irritation is of low concern based on mild, reversible corneal opacity, iritis and conjunctival irritation in 3 rabbits.